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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,686	07/31/2001	Stephen Alister Locarnini	37921-151956	7052
23973	7590	02/09/2006	EXAMINER	
DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996			PENG, BO	
			ART UNIT	PAPER NUMBER
			1648	
DATE MAILED: 02/09/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/831,686	Applicant(s) LOCARNINI ET AL.	
	Examiner Bo Peng	Art Unit 1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 17 is/are pending in the application.
- 4a) Of the above claim(s) 1-9, 11, 12, 15 and 17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10 and 13 is/are rejected.
- 7) ☒ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. AU PP 7060.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/22/02&8/22/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Restriction election

1. The Office acknowledges the receipt of Applicant's election, filed on January 13, 2006. Applicant elects the invention Group VI, claims 10 and 13, for prosecution, with traverse. Applicant also elected the species G112R mutant for examination. The traversal is on the ground(s) that mutations in the HBsAg of Group VI (claim 10) are overlapped with those in the DNA polymerase of Group VIII (claim 12) because their genes are overlapped in the genome and are transcribed from different reading frames. Therefore, rejoinder of Group VIII with elected Group VI is requested. Applicant's traversal is fully considered but is unpersuasive for the following reasons: Although a part of HBV polymerase gene is overlapped with HBsAg gene in their genome, the claimed HBV variants of Group VI and VIII of the instant application are divergent. The scope of Invention Group VI differs from that of Group VIII. The elected species G112R of Group VI, claim 10, for example, is not overlapped with any mutations listed in the Group VIII, claim 12. Therefore, the requirement is still deemed proper.
2. Applicant also requests the Office to examine all mutations of claim 10 since these mutations result in variants of HBV resistant to current chemotherapeutic agents and/or anti-HBV antibodies. Applicant's argument is unpersuasive for the following reasons: Like all HBV variants in the art, the claimed HBsAg variants result in resistant to current chemotherapeutic agents and/or anti-HBV antibodies. However, it would represent an undue burden for the Office to search all claimed species because they are not co-extensive of each other. The Examiner's requirement under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits is proper.

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3. Accordingly, claims 1-13, 15 and 17 are pending. Claims 1-9, 11, 12, 15 and 17 are withdrawn from consideration as being directed to a nonelected invention. Claims 10 and 13 are examined in the instant Office Action. Applicant's election of the species G112R mutant of claim 10 for examination is acknowledged. This restriction is made FINAL.

Specification

4. Applicant is required to update the status (pending, allowed, etc.) of all parent priority applications in the first line of the specification. The status of all citations of US filed applications in the specification should also be updated where appropriate.

Information Disclosure Statement

5. The information disclosure statements, submitted on April 22, 2002 and August 22, 2005, are in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements have been considered by the examiner. An initialed and dated copy of Applicant's IDS form 1449 is attached to the instant Office Action.

Foreign Priority

6. Receipt is acknowledged of papers and the certified copy of AU Application No. PP 7060 submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim objections

7. Claim 10 is objected to because of the following informality: It is noted that "S196W" in claim 10 appears to be a typo, because a W should be at position 196 of HBsAg of a wild type HBV. Appropriate correction is required.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office Action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 10 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Takeshima (1985) and Norder (1993).

10. Claims 10 and 13 are drawn to a variant HBV or variant HBsAg from said variant HBV comprising a mutation selected from the list consisting of G112R.

11. Takeshima teaches a variant HBsAg, called pHBR53, has a change of G112R in a relatively hydrophilic region of the HBsAg protein [See Figure 4, construct (5) adr, pHBR53, position 112].

12. Norder shows that two HBsAg variants, pADR1 and pADRRen, have the change of G112R in their HBsAg proteins (See Figure 2).

13. Therefore, the instant claim is anticipated by Takeshima and Norder.

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14. Claims 10 and 13 are rejected under 35 U.S.C. 102(a) as being anticipated by Grethe (1998).

15. Grethe discloses two HBV variants, F 2 and F4, which contain the change of G112R in their HBsAg proteins (see Figure 1). Therefore, claims 10 and 13 are anticipated by Grethe.

Remarks

16. No claim is allowed.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Bo Peng, Ph.D.
January 31, 2006


JEFFREY STUCKER
PRIMARY EXAMINER